

• • • • •

: Consolidated C.A. No. 10-cv-05954(WHW)

This consolidated action arises out of Defendants having filed Abbreviated New Drug Applications (“ANDAs”) with the Food and Drug Administration (the “FDA”) seeking approval to sell generic versions of the highly successful HIV drug PREZISTA® (also known by its

NOT FOR PUBLICATION

compound name, darunavir) 75 mg, 150 mg, 300 mg, 400 mg, and 600 mg products owned by the Janssen Plaintiffs and the Government Plaintiffs. J. Pls.’ Opening Markman Br. at 1 (ECF No. 185).

The Janssen Plaintiffs dispute two claim terms of U.S. Patent No. 7,700,645 (the “‘645 Patent”) and one claim term of U.S. Patent No. 7,772,411 (the “‘411 Patent”). The ‘645 Patent claims the ethanolate form of the drug that Janssen developed and sells as PREZISTA®. *Id.* The ‘411 Patent is directed to a process for manufacturing the compound (3R,3aS,6aR)-hexahydrofuro[2,3-b]furan-3-yl(1S,2R)-3-[[[(4-aminophenyl)sulfonyl](isobutyl)amino-1-benzyl-2-hydroxypropyl]-carbamate, which is also known as darunavir, the drug in both PREZISTA® and Mylan’s generic version of PREZISTA®. J. Pls.’ ‘411 Opening Markman Br. at 4 (ECF No. 307).

The U.S. Government and University of Illinois are co-owners of U.S. Patent No. 7,470,506 (the “‘506 Patent”). These Government Plaintiffs dispute four terms in Claim 1 of the ‘506 patent with Defendants. The ‘506 Patent covers methods of using the active ingredients in the drug PREZISTA® to treat HIV-infected mammals. Gov. Pls.’ Opening Markman Br. at 2 (ECF No. 187).

On September 15, 2011, this Court consolidated the patent infringement actions brought by the Janssen Plaintiffs for the purposes of pretrial proceedings and trial. ECF No. 71. On September 28, 2011, this Court also consolidated the Janssen actions with the patent infringement actions brought by the Government Plaintiffs for the purposes of pretrial proceedings, including the *Markman* hearing. ECF No. 79.

With respect to the ‘506 and ‘645 Patents, the parties exchanged Preliminary Claim Constructions on April 24, 2012. On April 27, 2012, the Janssen Plaintiffs served Amended Preliminary Claim Constructions. On May 22, 2012, the parties filed a Joint Claim Construction

NOT FOR PUBLICATION

and Prehearing Statement. ECF No. 175. The parties filed their opening *Markman* briefs on July 11, 2012, ECF Nos. 185, 186, 187, and their responsive *Markman* briefs on September 24, 2012, ECF Nos. 212, 213, 214. With respect to the ‘411 Patent, the parties filed a Joint Claim Construction and Prehearing Statement on March 22, 2013, ECF No. 299, filed their opening *Markman* briefs on April 4, 2013, ECF Nos. 307, 308, and filed their responsive *Markman* briefs on May 10, 2013, ECF Nos. 335, 336.

It should be noted that when this action was initially filed, it included claims by Plaintiffs (including G.D. Searle, LLC) against Defendants regarding U.S. Patent Nos. 5,843,946; 6,248,775 B1; RE42,889 E; and RE43,596 (collectively, the “Searle Patents”). Between April 15, 2013 and July 15, 2013, Defendants converted their Paragraph IV certifications with respect to the Searle Patents to Paragraph III certifications, informing the FDA that they would not seek approval of their proposed generic products until after the expiration of the Searle Patents and their associated exclusivities. The submission of the Paragraph III certifications to the FDA resolved the parties’ dispute over the Searle Patents, and this Court “so ordered” three dismissal stipulations as to the Searle Patents, as well as a stipulation removing G.D. Searle, LLC as a named party in the case. *See* ECF Nos. 378, 392, 415, 429.

STANDARD OF REVIEW

Claim construction is a legal issue for the Court. *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 976-78 (Fed. Cir. 1995) (en banc), *aff’d*, 517 U.S. 370 (1996). To construe claim terms, a court should first look to intrinsic evidence—the claims themselves, the specification and the prosecution history. *Philips v. AWH Corp.*, 415 F.3d 1303, 1314 (Fed. Cir. 2005) (en banc). The starting point of any analysis is the words of the claim. *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996). “When construing patent claims, there is a heavy presumption

NOT FOR PUBLICATION

that the language in the claim carries its ordinary and customary meaning amongst artisans of ordinary skill in the relevant art at the time of the invention.” *Housey Pharm., Inc. v. AstraZeneca UK Ltd.*, 366 F.3d 1348, 1352 (Fed. Cir. 2004). The term’s usage in the claim provides insight into its meaning, and claim terms must be interpreted in the context of the claims describing the patented invention. *Kyocera Wireless Corp. v. Int’l Trade Comm’n*, 545 F.3d 1340, 1347 (Fed. Cir. 2008).

The specification is particularly important in claim construction. “[C]laims must be read in view of the specification, of which they are a part.” *Phillips*, 415 F.3d at 1315 (quoting *Markman*, 52 F.3d at 979); *see also Metabolite Labs., Inc. v. Lab. Corp. of Am. Holdings*, 370 F.3d 1354, 1360 (Fed. Cir. 2004) (“In most cases, the best source for discerning the proper context of claim terms is the patent specification wherein the patent application describes the invention.”). When a patentee sets forth a definition of the disputed claim term in the specification, that definition “controls the meaning of [the claim term], regardless of any potential conflict with the term’s ordinary meaning[.]” *3M Innovative Props. Co. v. Avery Dennison Corp.*, 350 F.3d 1365, 1374 (Fed. Cir. 2003). Courts may also consider a patent’s prosecution history—the complete record of all proceedings before the U.S. Patent and Trademark Office (“PTO”) that led to the award of the patent. *Vitronics*, 90 F.3d at 1582.

After intrinsic evidence, a court may look to extrinsic evidence, including dictionary definitions, technical treatises or expert testimony. Expert testimony may provide useful background information, but “opinion testimony on claim construction should be treated with the utmost caution.” *Vitronics*, 90 F.3d at 1585. Such testimony “may only be relied upon if the patent documents, taken as a whole, are insufficient to enable the court to construe disputed claim terms. Such instances will rarely, if ever, occur.” *Id.*

NOT FOR PUBLICATION**DISCUSSION****I. The ‘645 Patent**

The Janssen Plaintiffs have asserted Claims 1-8 of the ‘645 patent against Defendants. J. Pls.’ Opening Markman Br. at 18-24 (ECF No. 185). The terms in dispute are “solvate” and “ethanolate solvate of the compound (3R,3aS,6aR)-hexahydrofuro[2,3-b]furan-3-yl(1S,2R)-3-[[[4-aminophenyl)sulfonyl](isobutyl)amino]-1-benzyl-2-hydroxypropylcarbamate” (the “Solvate Phrase”).

a. “Solvate”

The Janssen Plaintiffs argue that “solvate” should be defined according to the definition in the patent specification as “a crystal form that contains stoichiometric or non-stoichiometric amounts of solvent.” *Id.* at 7; *id.*, Ex. 2 at col. 4:45-47. Defendants claim that “solvate” should be defined as “a crystalline form that contains solvent incorporated at a regular position in its lattice structure.” Defs.’ Opening Markman Br. at 1, 14 (ECF No. 186). This Court adopts the Janssen Plaintiffs’ proposed construction of “solvate,” and this same construction will apply to the use of “solvate” in the Solvate Phrase, as discussed later in this Opinion.

Defendants contend that the Janssen Plaintiffs’ construction is based on a single statement from the ‘645 Patent specification, whereas the remainder of the intrinsic evidence shows that the claims were further narrowed during prosecution. *Id.* at 2. Defendants support their construction by relying on the specification’s discussion of other terms, the prosecution history, and the opinion of their expert, Dr. Laird. *Id.* at 2, 14-15.

With regard to the specification’s discussion of other terms, Defendants point to the definition of pseudopolymorphs as “polymorphic crystalline forms that have solvent molecules incorporated in their lattice structures.” *Id.* at 8; J. Pls.’ Opening Markman Br., Ex. 2 at col. 4:48-50 (ECF No. 185). Defendants also highlight the definition of crystalline as referring to “a form in

NOT FOR PUBLICATION

which the position of the molecules relative to one another is organized according to a three-dimensional lattice structure.” *Id.* at col. 4:37-39; Defs.’ Opening Markman Br. at 9 (ECF No. 186). Defendants argue that these definitions, among others, show that the invention intended to be covered by the ‘645 Patent “excludes polymorphs in which the solvent molecules are not incorporated within the lattice structure.” *Id.*

With regard to the prosecution history, Defendants primarily argue that the claims of the ‘645 Patent, as originally filed, were broadly directed to several different solvates of darunavir. *Id.* at 10. The Examiner subsequently issued an Office Action requiring the applicants to select a single invention. *Id.* The applicants then allegedly selected the ethanolate solvate of darunavir (i.e. a crystalline form of darunavir wherein the solvent is incorporated into the lattice structure) to further narrow down the claims. *Id.* at 10-11.

Defendants’ argument surrounding their proposed construction of the term “solvate” must fail. The Federal Circuit has clearly and repeatedly directed courts to the patent specification for guidance. *See, e.g., Vitronics*, 90 F.3d at 1582 (“The specification acts as a dictionary when it expressly defines terms used in the claims”); *Sinorgchem Co., Shandong v. Int’l Trade Comm’n*, 511 F.3d 1132, 1136 (Fed. Cir. 2007) (“[Federal Circuit] opinions have repeatedly encouraged claim drafters who choose to act as their own lexicographers to clearly define terms used in the claims in the specification.”); *Honeywell Int’l, Inc. v. Universal Avionics Sys. Corp.*, 493 F.3d 1358, 1361 (Fed. Cir. 2007) (“[T]he patentee’s definition governs, even if it is contrary to the conventional meaning of the term.”) (citation omitted).

Extrinsic evidence, including the opinion of Defendants’ expert, Dr. Laird, cannot be used to contradict the express definition in the specification. *Honeywell*, 493 F.3d at 1361; *Vitronics*, 90 F.3d at 1584 (noting that expert testimony “may not be used to vary or contradict the claim

NOT FOR PUBLICATION

language . . . [or] the import of other parts of the specification.”) The Federal Circuit has also frequently reiterated that the patent specification, and not expert testimony, is the single best guide to determining the meaning of a disputed claim term. *See Phillips*, 415 F.3d at 1315; *General Protecht Group, Inc. v. Int’l Trade Com’n*, 619 F.3d 1303, 1310 (Fed. Cir. 2010).

That being said, the rest of the specification and prosecution history are relevant to this inquiry. *See Chimie v. PPG Indus., Inc.*, 402 F.3d 1371, 1384 (Fed. Cir. 2005) (“The purpose of consulting the prosecution history in construing a claim is to ‘exclude any interpretation that was disclaimed during prosecution.’”) (citation omitted); *Omega Eng’g, Inc. v. Raytek Corp.*, 334 F.3d 1314, 1324 (Fed. Cir. 2003) (if inventor “unequivocally disavowed a certain meaning to obtain his patent, the doctrine of prosecution disclaimer attaches and narrows the ordinary meaning of the claim congruent with the scope of the surrender”); *Howmedica Osteonics Corp. v. Zimmer, Inc.*, No. 05-897 (WHW), 2007 WL 1231773, at *3 (D.N.J. Apr. 23, 2007) (summarizing authority).

Defendants’ arguments regarding the patent specification’s discussion of other terms do nothing to alter that fact that the specification does explicitly define “solvate.” J. Pls.’ Opening Markman Br., Ex. 2 at col. 4:45-47 (ECF No. 185). Defendants even acknowledge that definition. Defs.’ Opening Markman Br. at 9 (ECF No. 186) (“[T]he patent describes ‘solvate’ as ‘a crystal form that contains either stoichiometric or nonstoichiometric amounts of solvent.’”).

The rest of the specification does not support Defendants’ contention that the patent was narrowed. As an example, Defendants point to the definitions of the terms “pseudopolymorphs” and “crystalline,” yet neither of these alters the definition of the term “solvate” or mentions that the solvent is required to be incorporated in a lattice at “regular intervals” or in a “regular position.” J. Pls.’ Responsive Markman Br. at 12 (ECF No. 214).

NOT FOR PUBLICATION

The prosecution history does not appear to support Defendants' claim that the solvent molecules must be incorporated in a "regular position" or at "regular intervals." As Janssen Plaintiffs argue, the restriction requirement and election of ethanolate discussed in the prosecution history do not alter the meaning of "solvate." *Id.* at 14. The limitation on "solvate" to only include solvates in which the molecules are incorporated in the lattice at "regular intervals" or in a "regular position" was not discussed during the prosecution history. *Id.* "Ethanolate" concerns the identity of the solvent, and not the position of the molecules within the solvate. *Id.* This election is fully reflected in the specification and claims limitations which refer to an "ethanolate solvate" and the requirement of having a "ratio of compound to ethanol of about 1:1." *Id.*

This Court is also mindful of the Federal Circuit's admonition "that while proper claim construction requires an examination of the written description and relevant prosecution history to determine the meaning of claim limitations, additional limitations may not be read into the claims." *Storage Tech. Corp. v. Cicso Sys., Inc.*, 329 F.3d 823, 831 (Fed. Cir. 2003). *See also In re Donaldson Co.*, 16 F.3d 1189, 1195 (Fed. Cir. 1994) (noting the "general claim construction principle that limitations found only in the specification of a patent or patent application should not be imported or read into a claim"). Consequently, any possible limitations found in the prosecution history, assuming they even exist, should not be read into the claims.

b. The "Solvate Phrase"

The Janssen Plaintiffs argue that in light of the explicit definition of "solvate," the remainder of the Solvate Phrase requires no construction. J. Pls.' Opening Markman Br. at 18 (ECF No. 185). Defendants contend that the Solvate Phrase should be interpreted as meaning a "crystalline form of darunavir that has ethanol molecules incorporated at a regular position in its lattice structure." Defs.' Opening Markman Br. at 7 (ECF No. 186).

NOT FOR PUBLICATION

The Court adopts the Janssen Plaintiffs' argument that the definition of "solvate" found above in Section I(a) should apply to the use of "solvate" in the Solvate Phrase, and as a result no further construction of the "Solvate Phrase" is needed.

The Federal Circuit has held that when interpreting a phrase in claim construction, a court should not "disregard the established meanings of the individual words." *Altiris, Inc. v. Symantec Corp.*, 318 F.3d 1363, 1372 (Fed. Cir. 2003) (holding that the district court erred in not considering the meaning of the individual words of the phrase at issue). Defendants argue that looking to other intrinsic evidence is necessary to construe the Solvate Phrase, but given that a "word or phrase used consistently throughout a claim should be interpreted consistently," *Rexnord Corp. v. Laitram Corp.*, 274 F.3d 1336, 1342 (Fed. Cir. 2001) (internal citation omitted), and the definition of "solvate" found above, Janssen Plaintiffs are correct that the remainder of the Solvate Phrase requires no further construction. J. Pls.' Opening Markman Br. at 18 (ECF No. 185). The only other terms in addition to "solvate" in the Solvate Phrase are "ethanolate" and the "compound (3R,3aS,6aR)-hexahydrofuro[2,3-b]furan-3-yl(1S,2R)-3-[[4-(4-aminophenyl)sulfonyl](isobutyl)amino]-1-benzyl-2-hydroxypropylcarbamate." The ordinary meanings of these terms unambiguously identify the compound being claimed and no further construction by this Court is required.

II. The '411 Patent

The Janssen Plaintiffs have asserted Claim 1 of the '411 Patent against Mylan Pharmaceuticals Inc. and Mylan Inc. ("Mylan Defendants"). J. Pls.' '411 Opening Markman Br. at 1 (ECF No. 307). The term in dispute is "compound of formula (6)."

The Janssen Plaintiffs argue that "compound of formula (6)" should be defined according to the explicit definition in Claim 1 and the patent specification as the graphic description of

NOT FOR PUBLICATION

darunavir¹ or the written formula for the same compound (which Janssen Plaintiffs claim are two ways of describing the same chemical compound):

In particular, (3R,3aS,6aR)-hexahydrofuro[2,3-b]furan-3-yl(1S,2R)-3-[[4-aminophenyl)sulfonyl](isobutyl)amino-1-benzyl-2-hydroxypropylcarbamate, herein referred to as compound of formula (6)

Id., Ex. 1 at col. 2:3-6. Mylan Defendants claim that “compound of formula (6)” should be defined as “crystalline form of (3R,3aS,6aR)-hexahydrofuro[2,3-b]furan-3-yl(1S,2R)-3-[[4-aminophenyl)sulfonyl](isobutyl)amino-1-benzyl-2-hydroxypropyl-carbamate” because the disclosures in the prosecution history support the conclusion that the scope of the term “compound of formula (6)” must be limited to crystalline darunavir. Mylan Defs.’ ‘411 Opening Markman Br. at 1, 4 (ECF No. 308). The Court agrees with Janssen Plaintiffs’ construction of “compound of formula (6).”

Specifically, Mylan Defendants contend that the Janssen Plaintiffs’ proposed construction only considers limited portions of the intrinsic evidence (i.e. portions of the ‘411 Patent specification and the claim language), whereas the remainder of the intrinsic evidence shows that the claim was further narrowed during prosecution. *Id.* at 5. Mylan Defendants support their construction by relying on the specification’s discussion of other terms, the prosecution history, and the opinion of their expert, Dr. Laird. *Id.* at 5-6, 7, 8.

With regard to the prosecution history, Mylan Defendants primarily argue that the definition of “compound of formula (6)” in the ‘411 Patent, as originally filed, included the graphic depiction of darunavir and the words “addition salts, polymorphic and/or pseudopolymorphic forms thereof; characterized in that said process comprises” *Id.* at 5. The Examiner

¹ The phrase “graphic form” or “graphic depiction” refers to the relevant image in the ‘411 Patent. *See J. Pls.’ ‘411 Opening Markman Br.*, Ex. 1 at col. 4:1-13 (ECF No. 307).

NOT FOR PUBLICATION

subsequently rejected the claim under 35 U.S.C. § 112, citing in part the lack of an enabling disclosure concerning the preparation of polymorphs and pseudopolymorphs. *Id.* The Janssen Plaintiffs then allegedly did not contest the Examiner's rejection, but instead amended the proposed claims by removing the words "polymorphic and/or pseudopolymorphic forms." *Id.* at 6. Mylan Defendants argue that as a result of Janssen Plaintiffs' removal of those words, the Examiner withdrew the rejection and issued a notice of allowability, and therefore Janssen Plaintiffs unequivocally relinquished "polymorphic and/or pseudopolymorphic forms" of darunavir to obtain allowance of what ultimately issued as the '411 Patent. *Id.* at 6-7. According to Mylan Defendants, it follows that a person of ordinary skill in the art would understand that, at most, the only form of darunavir described in the '411 Patent, but not relinquished, is crystalline. Mylan Defs.' '411 Responsive Markman Br. at 6 (ECF No. 335).

With regard to the specification, Mylan Defendants point to the definitions of "polymorphic form" and "pseudopolymorphic form" and contend that given the prosecution history, one of ordinary skill in the art would not understand the claims of the patent to encompass the broad scope suggested by these definitions. *Id.* at 8. Mylan Defendants also contend that the Examples disclosed in the '411 Patent at most appear to describe the preparation of crystalline darunavir, particularly because in each Example the product is described as undergoing "crystallization." *Id.* at 9.

But Janssen Plaintiffs' proposed construction must prevail because the '411 Patent includes an explicit definition of "compound of formula (6)," and therefore that definition controls the meaning of the claim terms. *See 3M Innovative Props. Co. v. Avery Dennison Corp.*, 350 F.3d 1365, 1374 (Fed. Cir. 2003) (holding that where the patent defines a term that appears in the claims, that definition "controls the meaning of [the claim term]"); *Vitronics Corp. v. Conceptronic, Inc.*,

NOT FOR PUBLICATION

90 F.3d 1576, 1582 (Fed. Cir. 1996) (“The specification acts as a dictionary when it expressly defines terms used in the claims”); *Becton, Dickinson & Co. v. Tyco Healthcare Grp.*, 616 F.3d 1249, 1254 (Fed. Cir. 2010) (“Claim construction begins and ends in all cases with the actual words of the claim.”) (internal citation omitted). Claim 1 itself defines the “compound of formula (6)” by its graphic depiction, and the specification defines “compound of formula (6)” using the same graphic depiction multiple times, as well as using its written formula. Furthermore, none of the steps of the claimed process for producing “compound of formula (6)” involves crystallization of the compound of formula (6). There is no indication in the ‘411 Patent that the “compound of formula (6)” must be the crystalline form of darunavir.

The prosecution history does not support Mylan Defendants’ claim that the definition of “compound of formula (6)” must only include the crystalline form. As Janssen Plaintiffs argue, the deletion of the words “polymorphic and/or pseudopolymorphic forms” in the prosecution history does not appear to alter the meaning of “compound of formula (6).” J. Pls.’ ‘411 Responsive Markman Br. at 5 (ECF No. 307). Before the amendment to the claim, “compound of formula (6)” meant the compound of darunavir, represented graphically or in words by its chemical formula. Nothing that happened during prosecution limits that compound to a crystalline form.

Mylan Defendants’ argument is further complicated by the assertion that deleting the words “polymorphic and/or pseudopolymorphic forms” narrowed the meaning of “compound of formula (6)” to exclude “polymorphic and/or pseudopolymorphic forms.” However, the specification plainly defines “polymorphic form” to include “crystalline form[s]” of the compound of formula (6), J. Pls.’ ‘411 Opening Markman Br., Ex. 1, col. 17:27-30 (ECF No. 307), and Mylan Defendants do not seek a construction that excludes crystalline forms of “compound of formula (6),” but rather a construction that *requires* a crystalline form of that compound. As a result, Mylan

NOT FOR PUBLICATION

Defendants' proposed construction is quite strained, and their rebuttal that "not all crystalline forms are polymorphic forms" is a weak counterargument that does nothing to explain how narrow they intend the exclusion of "polymorphic forms" to be.

The rest of the specification does not support Mylan Defendants' assertion that the patent was narrowed. Their arguments regarding the patent specification do nothing to alter that fact that the specification does explicitly define "compound of formula (6)," both graphically and in words. Mylan Defendants even acknowledge that definition. Mylan Defs.' '411 Opening Markman Br. at 7 (ECF No. 308) ("The specification further states, in relevant part, that '(3R,3aS,6aR)-hexahydrofuro[2,3-b]furan-3-yl(1S,2R)-3-[(4-aminophenyl)sulfonyl](isobutyl)amino-1-benzyl-2-hydroxypropylcarbamate' is referred to in the patent as 'compound of formula (6)'. . . . A person of ordinary skill in the art would generally understand the chemical formula [recited above] to disclose the compound darunavir.").

With regard to Mylan Defendants' argument that the definition of "compound of formula (6)" must only extend to the crystalline form because the Examples disclosed in the '411 Patent appear to describe the preparation of crystalline darunavir, that argument must fail. It is well settled that "examples appearing in the specification will not generally be read into the claims," *In re Omeprazole Patent Litig.*, 483 F.3d 1364, 1372 (Fed. Cir. 2007), and the Federal Circuit "has cautioned against limiting the claimed invention to . . . specific examples in the specification." *Verizon Serv. Corp. v. Vonage Holdings Corp.*, 503 F.3d 1295, 1303 (Fed. Cir. 2007). *See also Silicon Graphics, Inc. v. ATI Techs., Inc.*, 607 F.3d 784, 792 (Fed. Cir. 2010) ("A construing court's reliance on the specification must not go so far as to import limitations into claims from examples . . . appearing only in a patent's written description . . . unless the specification makes

NOT FOR PUBLICATION

clear that the patentee . . . intends for the claims and the embodiments in the specification to be strictly coextensive.”) (citation omitted).

Mylan Defendants rely on expert testimony for the viability of their argument that the deletion of the words “polymorphic and/or pseudopolymorphic forms” from the claim must result in a definition of “compound of formula (6)” that necessarily includes only the crystalline form of darunavir. But as already established, expert testimony cannot be used to contradict the express definition in the specification. *Honeywell*, 493 F.3d at 1361; *Vitronics*, 90 F.3d at 1584 (noting that expert testimony “may not be used to vary or contradict the claim language . . . [or] the import of other parts of the specification.”). Because “compound of formula (6)” is expressly defined in the patent specification, Dr. Laird’s expert testimony contradicting that express definition is irrelevant.

III. The ‘506 Patent

The ‘506 Patent involves a different set of Plaintiffs, the U.S. Government and the University of Illinois (“Government Plaintiffs”). Claim 1 of the ‘506 Patent contains the disputed terms. Claim 1 reads, with the disputed terms in italics:

A method of treating a HIV-infected mammal who has *developed resistance to HIV treatments*, the method comprising (i) *determining whether the mammal has developed resistance to HIV treatments*; (ii) *administering* to the HIV-infected mammal *an effective amount* of a compound of the formula; and (iii) administering at least one antiviral agent selected from the group consisting of ritonavir, indinavir, amprenavir and saquinavir; whereby the HIV-infected mammal is treated.

Gov. Pls.’ Opening Markman Br. at 3 (ECF No. 187). Claim 1 is directed to treating an HIV-infected mammal with darunavir, in combination with at least one other antiviral agent, to minimize the likelihood of developing resistance to HIV treatments. *Id.* at 3-4.

Defendants initially identified three terms as requiring construction:

- “[D]eveloped resistance to HIV treatments”

NOT FOR PUBLICATION

- “[D]etermining whether the mammal has developed resistance to HIV treatments”
- “[E]ffective amount”

The Teva Defendants belatedly submitted the term “administering” for construction.² *Id.* at 7.

Defendants have generally taken the position that none of the above claim terms actually require construction, but are subject to their “plain and ordinary meaning.” *Id.* Government Plaintiffs, on the other hand, argue that the terms do require construction, and their proposed constructions are grounded in the patent specification, prosecution history and extrinsic evidence. *Id.* at 7-8.

a. “[D]eveloped resistance to HIV treatments”

Government Plaintiffs contend that the phrase “developed resistance to HIV treatments” is not a claim limitation because it is contained in the preamble of the claim and not in the claim itself. They argue in the alternative that, if the Court finds that the phrase is a claim limitation, the phrase should be construed as follows: “The subject mammal is infected with at least one clinical isolate of HIV, the replication of which is not optimally suppressed by administration of anti-HIV drug treatment with one or more anti-HIV drugs.” *Id.* at 8-9. Defendants argue that the phrase should serve as a claim limitation and advocate interpreting the phrase according to its “plain and ordinary meaning.” Defs.’ Opening Markman Br. at 18 (ECF No. 186).

i. Preamble Dispute

Government Plaintiffs argue that the preamble is not a limitation of the ‘506 Patent since it is not a requirement of the patent for mammals with HIV to have developed resistance to HIV treatments. Government Plaintiffs also point to the specification and prosecution history for examples demonstrating that the ‘506 Patent was not so limited. Gov. Pls.’ Opening Markman Br.

² The other Defendants joined in Teva’s submission in their responsive Markman briefs. The issue of timeliness will be discussed in detail later in this section.

NOT FOR PUBLICATION

at 9-10 (ECF No. 187). The Court agrees with Government Plaintiffs that the preamble is not a limitation of the '506 Patent.

Government Plaintiffs primarily rely on a sentence in the 2008 Reply to Office Action, which states that “Applicants are no longer relying on the preamble of the claims for patentability.” *Id.* at 10. Government Plaintiffs interpret this phrase as an express statement that the language of the preamble did not operate as a claim limitation for purposes of patentability. *Id.* Government Plaintiffs also point to the recognition in a 2004 Office Action by the Examiner that the “instantly claimed invention is directed at a method of preventing the development of drug resistance in an HIV-infected mammal.” *Id.* at 9-10.

Defendants contend that the preamble should serve as a claim limitation because it gives “meaning and purpose” to the manipulative steps described in the body of the claim—i.e. that it demonstrates the “stated objective” of the invention. Defs.’ Opening Markman Br. at 17 (ECF No. 186). In the absence of the stated objective, Defendants claim that the language would serve no purpose. *Id.* In further support of their argument, Defendants point out that the phrase “developed resistance to HIV treatments” appears in both the preamble and in the body of the claim. *Id.*

Finally, Defendants argue that the preamble is limiting because the claim elements rely on and derive antecedent basis from the preamble. *Id.* at 18. As an example, the body of Claim 1 refers to “*the* mammal” and “*the* HIV-infected mammal.” Defendants maintain that the use of “the” indicates that these terms derive antecedent basis from the phrase “*a* HIV-infected mammal who has developed resistance to HIV treatments” in the preamble. *Id.*

The Court finds that the preamble is not a claim limitation because the historical rule involving the construction of preambles is that preamble language acts as a limitation on the claim *only* when it is necessary to give life, meaning, and vitality to it. *Kropa v. Robie*, 187 F.2d 150,

NOT FOR PUBLICATION

152 (Ct. of Customs and Pat. App. 1951). “A preamble has the import that the claims as a whole suggest for it.” *Bell Communications Research, Inc. v. Vitalink Communications Corp.*, 55 F.3d 615, 620 (Fed. Cir. 1995). Where a patentee uses a preamble only to state a purpose or intended use for the invention, the preamble is not a claim limitation. *Rowe v. Dror*, 112 F.3d 473, 478 (Fed. Cir. 1997). But if limitations in the body of a claim rely on and derive antecedent basis from the preamble, the preamble acts as a necessary component for the claimed invention. *Seachange Int’l, Inc. v. C-COR, Inc.*, 413 F.3d 1361, 1376 (Fed. Cir. 2005).

The preamble at issue here is not necessary to give “life, meaning, or vitality” to the claim. Rather, the preamble should be reviewed to state one purpose or use for the invention. *Rowe*, 112 F.3d at 487. The patent specification makes clear that the covered invention is also intended to *prevent*, and not only inhibit, the emergence of drug resistance in an HIV-infected mammal. *See, e.g.*, Gov. Pls.’ Opening Markman Br., Ex. 1 at col. 15:7-11 (ECF No. 187); *id.*, Ex.1 at col. 4:47-51 (“The present invention also provides a method of preventing the development of drug resistance of HIV in an HIV-infected mammal”); *id.*, Ex. 1 at 26:51-57; *id.*, Ex. 1 at 3:30-37 (“There is also a need for a method of devising a long-term therapeutic regimen that minimizes the likelihood that resistance will occur in a disease involving a replicating biological entity. Moreover, there is a need for a method of preventing or inhibiting the development of drug resistance in such diseases. The present invention provides such methods”). *See also id.* at 9.

The prosecution history further supports Government Plaintiffs’ construction. In a 2004 Office Action, the Examiner specifically recognized that “[t]he instantly claimed invention is directed at a method of preventing the development of drug resistance in an HIV-infected mammal” *Id.* at 9-10.

NOT FOR PUBLICATION

Defendants’ argument that terms in the body of the claim derive antecedent basis from the preamble, and that the preamble should be read as a claim limitation, is rejected. “If the body of the claim describes a structurally complete invention such that deletion of the preamble phrase does not affect the structure or the steps of the claimed invention, the preamble is generally not limiting unless there is clear reliance on the preamble during prosecution to distinguish the claimed invention from the prior art.” *Intirtool, Ltd. V. Texar Corp.*, 369 F.3d 1289, 1295 (Fed. Cir. 2004) (internal citations omitted). Government Plaintiffs made the express statement during prosecution that they “are no longer relying on the preamble of the claims for patentability.” Gov. Pls.’ Opening Markman Br. at 10 (ECF No. 187). It follows that Defendants’ arguments fail.

b. “[D]etermining whether the mammal has developed resistance to HIV treatments”

Government Plaintiffs maintain that this phrase should be construed as “[e]mploying an assay, including those described in the specification of the ‘506 patent, to determine whether the subject mammal is infected with at least one clinical isolate of HIV, the replication of which is not optimally suppressed by administration of anti-HIV drug treatment with one or more anti-HIV drugs.” Gov. Pls.’ Opening Markman Br. at 12 (ECF No. 187). Government Plaintiffs argue that this construction is supported by the patent specification, which, along with the prosecution history, describes the patented invention in terms of its impact on HIV clinical isolates. *Id.* They further allege that the specification and prosecution history describe several tests or “assays” to determine whether a clinical isolate is HIV treatment resistant. *Id.*

Defendants argue that this term should have its plain and ordinary meaning, which is: “[T]he subject mammal is infected with at least one clinical isolate of HIV, the replication of which is not suppressed by administration of two or more anti-HIV drugs or which contains one or more mutations associated with the inability to suppress replication of the clinical isolate by

NOT FOR PUBLICATION

administration of two or more anti-HIV drugs, wherein the replication of the isolate or identification of mutations in the isolate is measured by any assay, including, but not limited to, genotypic and phenotypic assays.” Defs.’ Opening Markman Br. at 19 (ECF No. 186).

The Court adopts the Government Plaintiffs’ construction of the phrase “determining whether the mammal has developed resistance to HIV treatments.” Defendants’ argument would be contrary to the above construction that it is not a requirement of the ‘506 patent for mammals infected with HIV to have already developed resistance to HIV treatments, since Defendants’ interpretation presupposes that the subject mammal is already infected “with at least one clinical isolate of HIV.” *Id.* at 19. In addition, Defendants’ claimed “plain and ordinary” meaning is far from that; Defendants, like Government Plaintiffs, propose their own construction. Defendants’ construction also relies primarily on the testimony of their expert, Dr. Zingman, and finds little support in the specification or prosecution history. *See* Gov. Pls.’ Responsive Markman Br. at 6-8 (ECF No. 212).

The specification and prosecution history of the ‘506 patent describe the drug compound in terms of its effect on “clinical isolates” of HIV. *See, e.g., id.*, Ex. 1 at col. 27:39-43; *id.*, Ex. 5, Reply to Office Action at 18 (June 14, 2007). The specification further describes the suppression of such clinical isolates in terms of the optimal or effective suppression of the HIV virus “replication.” *Id.*, Ex. 1 at col. 3:26-36, col. 6:9-24. *See also id.* at 10-11. The specification states that a “suitable dose includes a dose or dosage that would be insufficient to completely suppress the growth of a wild-type or predecessor virus, but would be sufficient to inhibit or effectively suppress the growth of a mutant.” *Id.*, Ex. 1 at col. 26:36-40. The specification and prosecution history also specifically reference and describe several tests, or “assays,” used to determine whether a clinical isolate is HIV treatment resistant. *See, e.g., id.*, Ex. 1 at col. 40:53-45.

NOT FOR PUBLICATION

Consequently, Government Plaintiffs' construction is in line with the specification and prosecution history.

Defendants' proffered construction, on the other hand, asserts that a mammal would only be deemed to have "developed resistance" if it were infected with a clinical isolate that was not suppressed *at all* by the administration of two or more anti-HIV drugs. Defs.' Opening Markman Br. at 19 (ECF No. 186). There does not appear to be any support for this very narrow construction in the specification or prosecution history; Defendants rely largely on the opinion of their expert, Dr. Zingman. There is also little support for Defendants' contention that Claim 1 only applies to a mammal that has developed resistance to at least *two* previous treatments. While the phrase "HIV treatments" is indeed plural, "treatments" does not necessarily refer to the number of drugs used, nor does it necessarily connote that resistance to multiple drugs was required. The Court agrees with Government Plaintiffs that "treatments" could just as plausibly refer to the dosing regimen. *See* Gov. Pls.' Responsive Markman Br. at 9 (ECF No. 212). Finally, there is no reference to genotypic or phenotypic assays in the claims, and no such restriction appears in the patent specification.

c. "[E]ffective amount"

Government Plaintiffs argue that the phrase "effective amount" should be construed as "[a] dosage regimen of the claimed compound which, in combination with the other drugs claimed, provides optimal suppression of the replication of at least one clinical isolate of HIV in an infected mammal." Gov. Pls.' Opening Markman Br. at 13 (ECF No. 187). According to Government Plaintiffs, this definition is consistent with the patent specification, which states that a "suitable dose includes a dose or dosage which would be insufficient to completely suppress the growth of a wild-type or predecessor virus, but would be sufficient to inhibit or effectively suppress the

NOT FOR PUBLICATION

growth of a mutant.” *Id.*; *id.*, Ex. 1 at col. 26:36-40. Government Plaintiffs interpret this patent specification statement to mean that an effective amount of darunavir is an amount sufficient to effectively or optimally suppress drug resistant HIV mutant strains. *Id.* at 13.

Defendants propose that the phrase means: “A dosage regimen of the claimed compound that, in combination with the other drugs claimed, provides suppression of the replication of the clinical isolate of HIV with which the mammal is infected.” Defs.’ Opening Markman Br. at 23-24 (ECF No. 186). Defendants contend that their interpretation is in line with the “plain and ordinary meaning.” *Id.* at 24. They further argue that the patent specification never uses the word “optimal,” but suggests that “an effective amount can be any suitable dosage level that provides a therapeutic response.” *Id.* at 25; Gov. Pls.’ Opening Markman Br. at 13-14 (ECF No. 187).

The Court adopts the Government Plaintiffs’ construction of the term “effective amount,” which appears to be more closely in line with the specification and prosecution history. The phrase “effective amount” must be interpreted consistently with the previously-construed phrase, “determining whether the mammal has developed resistance to HIV treatments,” with “effective amount” being equivalent to an amount sufficient to effectively or optimally suppress the replication of at least one clinical isolate of HIV. *See supra* Section III(b).

Defendants’ construction finds little support in the specification or prosecution history, and relies primarily on the testimony of their expert, Dr. Zingman. *See* Defs.’ Opening Markman Br. at 24-26 (ECF No. 186). Defendants’ proposed construction is unpersuasive in that it gives no real meaning to the term “effective,” and rather simply describes an amount that provides any “suppression” at all. Expert testimony in claim construction should only be considered if the patent documents as a whole are insufficient to enable the court to construe disputed claim terms. *Vitronics*, 90 F.3d at 1585. That is not the case here, but even if the Court were to consider expert

NOT FOR PUBLICATION

testimony on this issue, Defendants’ proposed construction still must fail. Defendants’ expert, Dr. Zingman, claims that the term “optimal suppression” is “extremely vague and does not have an accepted meaning to the skilled person.” *Id.* at 24. On the other hand, Government Plaintiffs’ expert Dr. Murphy convincingly contends that in 1998, at the time the original patent application was filed, one of ordinary skill in the art would have understood that the goal of HIV drug therapy was “maximum suppression,” which is equivalent to optimal (or effective) suppression—i.e. reducing the viral load to its lowest detectable amount. Gov. Pls.’ Responsive Markman Br. at 7 (ECF No. 212).

d. “[A]dministering”

i. Admissibility Dispute

The Teva Defendants first amended their identification of disputed claims terms to add the term “administering” in the May 22, 2012 Joint Claim Construction Statement and Prehearing Statement. ECF No. 175. On June 1, 2012, Teva submitted a purported supplement to the parties’ Joint Statement, providing a preliminary proposed construction and supporting intrinsic and extrinsic evidence. The Government and University of Illinois Plaintiffs did not consent to adding this term to the list of disputed terms for the ‘506 patent. Gov. Pls.’ Opening Markman Br. at 14 (ECF No. 187). Teva’s June 1, 2012 submission was untimely under this Court’s Order, which set a due date of April 24, 2012 for the parties to submit their proposed claim constructions. ECF No. 144. The other defendants, Mylan and Lupin, joined in Teva’s submission in their Markman response brief. Defs.’ Responsive Markman Br. at 21-24 (ECF No. 213). Government Plaintiffs first request that the Court find that this term is not properly in dispute.

Despite the fact that this suit was originally filed in 2010, giving Teva adequate notice and time to identify any disputed claim terms, the Court exercises its discretion to consider arguments

NOT FOR PUBLICATION

as to the construction of this term. At the *Markman* hearing, Government Plaintiffs offered no reason why the claim should not be construed, and admitted that it had not suffered any prejudice due to the untimeliness of the submission. Both sides were able to fully brief the issue and the addition of the term has added no extra burden on the Court. *See Minton v. Nat'l Ass'n of Sec. Dealers, Inc.*, 336 F.3d 1373, 1379-80 (Fed. Cir. 2003).

ii. Construction

The Government Plaintiffs propose that the term “administering” should be interpreted to mean “[m]anaging or supervising the execution or use of the claimed compound(s) of the ‘506 patent.” Gov. Pls.’ Opening Markman Br. at 14 (ECF No. 187). Government Plaintiffs contend that this construction accords with the definition provided in Merriam-Webster’s Dictionary for “administer”: “to manage or supervise the execution, use or conduct of.” *Id.* at 15. They contend that this proposed construction “recognizes and encompasses the activities of doctors and other medical professionals who are involved in prescribing the claimed compounds or otherwise supervising the care of HIV-infected patients.” *Id.* at 16.

Defendants contend that the term should be interpreted to have its “[p]lain and ordinary meaning,” which is “[t]o provide externally for the purpose of delivering into the body.” Defs.’ Opening Markman Br. at 26 (ECF No. 186). Defendants assert that the ‘506 Patent specification uses the term “administering” “in conjunction with forms of external administration and explains that the compound is administered in a pharmaceutical composition,” and such use of the term refers only “to the form of the substance before it enters the mammal’s body, and not to any substance which may subsequently form inside the mammal’s body.” *Id.* at 26-27. Defendants state that the Government Plaintiffs chose a definition of “administer” from the Merriam-Webster Dictionary which is described as relating to a trust fund (i.e. “administer” a trust fund), rather than the definition of “administer” as “to give remedially,” which is more appropriate in a health care

NOT FOR PUBLICATION

context (i.e. “administer” a dose of medicine). Defs.’ Responsive Markman Br. at 21-22 (ECF No. 213).

The Court adopts the Government Plaintiffs’ construction of the term “administering.” The ‘506 Patent sets forth a method of treating an HIV-infected mammal that has developed resistance to HIV treatments—a method that involves prolonged contact, treatment and supervision of the mammal that is being treated pursuant to the patent. Government Plaintiffs’ construction of “administering” as “managing or supervising the execution or use of the claimed compound(s) of the ‘506 patent” is more in line with the overall purpose of the patent and the reality of what the patent is designed to do. Defendants’ proposed construction in the context of this patent, on the other hand, is overly literal and rigid and potentially removes the activities of medical professionals like doctors (who are not always necessarily involved in directly providing the medicine to their patients—a patient may put a pill in her mouth herself) from the purview of this patent. The Court cannot accept that view as a matter of reality. The Court finds that the construction of “administering” in the ‘506 Patent should recognize and encompass “the activities of doctors and other medical professionals who are involved in prescribing the claimed compounds or otherwise supervising the care of HIV-infected patients.” Gov. Pls.’ Opening Markman Br. at 16 (ECF No. 187).³

³ The Court makes no finding as to the effect of this construction of “administering” on the pre-ingestion and/or “change upon ingestion” issues discussed in the parties’ briefing. *See* Defs.’ Opening Markman Br. at 27 (ECF No. 186); Defs.’ Responsive Markman Br. at 23 n.24 (ECF No. 213); Gov. Pls.’ Opening Markman Br. at 16 (ECF No. 187); Gov. Pls.’ Responsive Markman Br. at 12 (ECF No. 212).

NOT FOR PUBLICATION

CONCLUSION

The disputed claim terms will be construed as determined in this Opinion.

October 9, 2013

/s/ William H. Walls
United States Senior District Judge